

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently Amended) A balloon catheter medical device that releases a drug by immediate release for the selective therapy of specific diseased tissue or an organ part to which said drug will bind, comprising such a drug which is lipophilic, water-insoluble and immediately releasable, adhered to a smooth surface of the balloon of said catheter that comes into contact with the diseased tissue or organ part, which adhered drug when pressed against said tissue or organ part at least for a short time, is immediately released into said tissue or organ part, ~~wherein the drug is adhered to said surface in a manner resulting in an amount of drug retained on said device of about 10% or less after a time period of said tissue contact which is equal to the time of contact during stent implantation in a vessel, and wherein the concentration of said drug on said surface is up to 5 µg/mm<sup>2</sup>.~~
2. (Previously Presented) The device according to claim 1, wherein said balloon catheter comprises a stent.
3. (Previously Presented) The device according to claim 2, wherein a balloon with preformed longitudinal folds is coated with the drug, and the inclination of said folds to refold is not lost after inflation.
4. (Previously Presented) The device according to claim 2, wherein a balloon is coated with said drug and comprises very smooth material to which drugs adhere sufficiently well to resist forces required for folding, essentially without damage.
5. (Previously Presented) The device according to claim 1, wherein said balloon catheter does not comprise a stent.

6. (Previously Presented) The device according to claim 2, wherein only the area covered by folds is coated with the drug that was dried after application.
7. (Previously Presented) The device according to claim 1, wherein the lipophilic drug is an inhibitor of cell proliferation or inflammatory processes, or an antioxidant.
8. (Previously Presented) The apparatus according to claim 7, wherein the drug used is paclitaxel or other taxane, rapamycin, tacrolimus, a corticoid, a sex hormone, a statin, an epothilone, probucol, a prostacyclin, or an angiogenesis inducer.
9. (Previously Presented) The apparatus according to claim 7, wherein the lipophilic drug is present as a dry solid or oil on the surface of the device.
10. (Previously Presented) The device according to claim 9, wherein the dosage form of the drug includes amorphous structures with particle sizes ranging from <0.1 micron to 5 microns that dissolve quickly due to their large surface area and despite the water-insolubility of the drug.
11. (Previously Presented) The device according to claim 1, wherein the lipophilic drug is embedded in a readily water-soluble matrix substance to achieve good adhesion to the surface of the device and improve absorption by the tissue.
12. (Previously Presented) The device according to claim 11, wherein said matrix substance is a low-molecular weight hydrophilic substance with a molecular weight <5000 D.
13. (Previously Presented) The device according to claim 1, wherein the lipophilic drug is absorbed to particles of or applied to the surface of the device with, a low-molecular weight matrix.

14. (Previously Presented) The device according to claim 1, having a surface additionally coated with a substance that influences the gliding quality of the device or that prevents blood coagulation.
15. (Previously Presented) A method for producing the device according to claim 1, comprising applying the lipophilic drug in a solution, suspension or emulsion medium using an immersion, spreading, or spraying process or an instrument which delivers a defined volume to the surface of the device to provide a coating and removing excess media and substances that adhere loosely to the surface.
16. (Previously Presented) The method according to claim 15, wherein the coating process is carried out repeatedly to achieve a reproducible increase of the active agent content using the same or a different solution, suspension, or emulsion medium and/or excipient.
17. (Previously Presented) The method according to claim 16, wherein ethanol, isopropanol, ethyl acetate, diethyl ether, acetone, dimethyl sulfoxide, dimethyl formamide, glycerin, water or a mixture thereof is used as solution, suspension, or emulsion medium.
18. (Previously Presented) The method according to claim 15, wherein a balloon folded ready for use is used as the drug carrier coated prior to or after sterilization with or without a crimped-on stent.
19. (Previously Presented) The method according to claim 18, wherein the balloon is coated with the lipophilic drug in unfolded condition and then is folded with a lubricating tool optionally wetted with a biocompatible, gliding agent.
20. (Previously Presented) The method according to claim 15, wherein a stent is attached prior to or after coating of the balloon catheter.

21. (Previously Presented) The method according to claim 15, wherein the completely coated device is sterilized using ethylene oxide.
22. (Previously Presented) A method of treating a vascular disease or circulation disturbance comprising administering a device of claim 1 to affected tissue.
23. (Previously Presented) A method of opening a passage in the body comprising administering a device of claim 1.
24. (Currently Amended) A balloon catheter having folds in its balloon, comprising a lipophilic, water-insoluble drug which binds to tissue, said drug being adhered to a smooth the balloon surface in a fashion wherein it is immediately released upon coming into contact with said tissue, wherein the balloon area covered with folds is coated with said drug which has been dried after application, and wherein the concentration of said drug on said surface is up to 5  $\mu\text{g}/\text{mm}^2$ .
25. (Previously Presented) The balloon catheter according to claim 24, further comprising a stent, a needle or a guiding wire.
26. (Previously Presented) The balloon catheter according to claim 24, comprising in its finally folded state a balloon coated with a low-viscosity active agent solution of said drug, by immersing, spraying or applying via a volume measuring device.
27. (Previously Presented) The balloon catheter according to claim 24, wherein the lipophilic drug is an inhibitor of cell proliferation or an inflammatory process, or an antioxidant.
28. (Previously Presented) The balloon catheter according to claim 27, wherein the drug is paclitaxel or other taxane, rapamycin, tacrolimus, a corticoid, a sex hormone, a statin, an

epothilone, probucol, a prostacyclin or an angiogenesis inducer.

- 29. (Previously Presented) The balloon catheter according to claim 27, wherein the lipophilic drug is present as a dry solid or oil on the surface of the balloon.
- 30. (Previously Presented) The balloon catheter according to claim 29, wherein the dosage form of the drug comprises amorphous structures with particle sizes ranging from <0.1 micron to 5 microns that dissolve fast due to their large surface area and despite the water-insolubility of the drug.
- 31. (Previously Presented) The balloon catheter according to claim 24, wherein said lipophilic drug is embedded in a readily water-soluble matrix substance to achieve good adhesion to the surface of the balloon and improved absorption by the tissue.
- 32. (Previously Presented) The balloon catheter according to claim 31, wherein said matrix substance is a low-molecular weight hydrophilic substance with a molecular weight <5000 D.
- 33. (Previously Presented) The balloon catheter according to claim 31, wherein said matrix substance is a contrast agent.
- 34. (Previously Presented) The balloon catheter according to claim 33, wherein said substance is an iodinated X-ray contrast agent.
- 35. (Previously Presented) The balloon catheter according to claim 34, wherein the drug is paclitaxel and the X-ray contrast agent is iopromide.
- 36. (Previously Presented) The balloon catheter according to claim 24, wherein said lipophilic drug is absorbed to a particle or applied to the surface of the device with a low-

molecular weight matrix.

37. (Previously Presented) The balloon catheter according to claim 24, having a surface additionally coated with a substance that influences the glidability of the device or that prevents blood coagulation.
38. (Previously Presented) A method for producing the coated balloon catheter according to claim 24, comprising applying the lipophilic drug in a solution, suspension or emulsion medium using an immersion, spreading, or spraying process or a volume measuring device to the surface of a folded balloon, and removing excess media and substances that adhere loosely to the surface.
39. (Previously Presented) The method according to claim 38, wherein the coating process is carried out repeatedly to achieve a reproducible increase of the active agent content using the same or a different solution, suspension, or emulsion medium and/or excipient.
40. (Previously Presented) The method according to claim 39, wherein ethanol, isopropanol, ethyl acetate, diethyl ether, acetone, dimethylsulfoxide, dimethylformamide, glycerol, water or a mixture thereof is used as solution, suspension, or emulsion medium.
41. (Previously Presented) The method according to claim 38, wherein a folded and substantially ready for use balloon is used as the drug carrier coated before or after sterilization with or without a crimped-on stent.
42. (Previously Presented) The method according to claim 38, wherein a stent is connected to the balloon catheter before or after coating.
43. (Previously Presented) The method according to claim 38, wherein the finally coated balloon catheter is sterilized using ethylene oxide.

44. (Previously Presented) A method for the treatment of a vascular disease or a dysfunction of circulation comprising administering a catheter of claim 24.
45. (Previously Presented) A method for opening a passage in the body comprising administering a catheter of claim 24.
46. (Previously Presented) A method for tumor treatment comprising administering a catheter of claim 24.
47. (Canceled)
48. (Canceled)
49. (New) A balloon catheter medical device that releases a drug by immediate release for the selective therapy of specific diseased tissue or an organ part to which said drug will bind, comprising such a drug which is lipophilic, water-insoluble and immediately releasable, adhered to a surface of the balloon of said catheter that comes into contact with the diseased tissue or organ part, which adhered drug when pressed against said tissue or organ part at least for a short time, is immediately released into said tissue or organ part, wherein the drug is adhered to said surface in a manner resulting in an amount of drug retained on said device of about 10% or less after a time period of said tissue contact which is equal to the time of contact during stent implantation in a vessel, and wherein the concentration of said drug on said surface is up to 5  $\mu\text{g}/\text{mm}^2$ .
50. (New) A balloon catheter medical device that releases a drug by immediate release for the selective therapy of specific diseased tissue or an organ part to which said drug will bind, comprising such a drug which is lipophilic, water-insoluble and immediately releasable, adhered to a surface of the balloon of said catheter that comes into contact with

the diseased tissue or organ part, which adhered drug when pressed against said tissue or organ part at least for a short time, is immediately released into said tissue or organ part, wherein the concentration of said drug on said surface is up to 5  $\mu\text{g}/\text{mm}^2$ .